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EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1655

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/826,316

Applicant(s)

CHARRIERE ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-136 is/are pending in the application.
- 4a) Of the above claim(s) 97-106 and 117-136 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 77-96 and 107-116 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/04;1/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on December 6, 2006.

Specification

The disclosure is objected to because of the following informality: An amendment to the first sentence of the specification should refer back to the prior application, since this application is a divisional application of United States Patent Application 09/902,266 000,000 filed 07/11/2001, now abandoned. Appropriate correction is required.

Election/Restrictions

Applicant's election with traverse of Group 3, Claims 77-96 and 107-116, in the reply filed on December 6, 2006 is acknowledged. The traversal is on the grounds that Applicant believes that a search and examination of Groups I and III would be substantially coextensive, since Group I is drawn to a regime or regimen for promoting regrowth of hair and/or retarding hair loss by administering the same designated composition as recited in Group III. Applicant further argues that elected Group III can occur as a result of the process described in Group I, that is increasing hair density can occur as a result of the promoting hair regrowth and/or retarding hair loss. Thereby, Applicant submits that it is likely that a search of the claims of elected Group III and those of Group I would be coextensive. This is not found fully persuasive because while

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promoting hair regrowth and/or retarding hair loss may beneficially increase hair density, it is not necessarily so. For instance, promoting hair regrowth and/or retarding hair loss may only provide for the lengthening of hair or increasing the growth rate of hair. Furthermore, the search of Group I along with Group III would be burdensome because the claimed method of Group I requires the search of additional terms and ingredients not required by the search of the claimed method of Group III, which is drawn to a method of increasing hair density and thus improving the quality of a head of hair; and, thus also treating alopecia. Applicant further argues that it is likely that a search of the claims of Group III relating to increasing hair density would be coextensive with the search of the claims of Groups II and V. However, this is not persuasive because it is not likely that a search of Group III would require the search of terms relating to increasing the mean diameter of strands of hair and decreasing the heterogeneity as required for the search of the invention of Group II or the search of terms related to inducing repigmentation of hair as required for the search of the invention of Group V.

Moreover, these methods are capable of separate manufacture, use or sale, as claimed, and are patentable (novel and unobvious) over each other (though they may be unpatentable because of the prior art) subjects. One would not have to practice the various methods at the same time to practice just one method alone.

The several inventions above are independent and distinct, each from the other. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further a reference which would anticipate the invention

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of one group would not necessarily anticipate or even make obvious another group.

Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 77-96 and 107-116 are under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 77, 78, 83-88, 93-96, 107, 108 and 113-116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klett-Loch (AA, US 6,013,279) in view of Schardt (NN, DE 10021310 A1).

Applicant claims a regime or regimen for increasing hair density comprising administering to an individual in need of such treatment, for such period of time as required to elicit the desired effect, a vitamin/metal salt cosmetic/pharmaceutical composition consisting essentially of a thus effective amount of an admixture of the antioxidants vitamin A, vitamin C, vitamin E and also zinc and selenium salts, formulated into a cosmetically/pharmaceutically acceptable, vehicle, diluent or carrier thereof. Applicant further claims the regime or regimen for increasing hair density as defined by Claim 77, said admixture also comprising vitamin B; said admixture also

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comprising iron in salt form; wherein the zinc salt is zinc gluconate, zinc oxide, zinc sulfate or zinc chloride; and, wherein the selenium salt is sodium selenite, selenocysteine or selenoyeast. Applicant further claims the method of Claims 77, 85 and 96 for increasing hair density and thus improving the quality and/or the appearance of a head of hair comprising the administration of a thus effective amount of the claim designated admixture, and claim designated process step of administration to an individual in need thereof of such treatment. Applicant further claims the method of Claims 77, 85 and 96 for increasing hair density and thus treating alopecia comprising the administration of a thus effective amount of the claim designated admixture, and claim designated process step of administration to an individual in need thereof of such treatment.

Klett-Loch teaches a method for increasing hair density comprising administering to a person in need thereof a composition consisting essentially of vitamin B; the antioxidant vitamins A (beta-carotene), C (calcium ascorbate, a salt of ascorbic acid) and E (alpha-tocopherol); selenium (selenium yeast); and, the sulfur-containing amino acid, cystine. See patent claims. The composition taught by Klett-Loch may be in the form of an emulsion, tablets, capsules, or gelatin capsules. See Column 4, line 34 to Column 5, line 44. In Column 2, lines 39-54, Klett-Loch teaches that the referenced composition stimulates the growth of hair; prevents or eliminates the loss of hair; accelerates multiphase, lengthy regrowth process, while avoiding a shrinkage of the hair follicles and thereby increasing hair density, preserves the health of the hair; improves

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the basic health of the hair; and increases hair density by either oral or topical application.

The teachings of Klett-Loch are set forth above. Klett-Loch teaches the instantly claimed invention except for wherein the admixture comprises a zinc salt and wherein the selenium salt is sodium selenite. However, it would have been obvious to one of ordinary skill in the art to add the claim-designated ingredients to the method taught by Klett-Loch to provide the instantly claimed regime or regimen because at the time the invention was made Schardt taught an aqueous hair lotion for controlling dandruff and alopecia containing lactic acid, citric acid, dex (panthenol), sodium selenite, zinc sulfate, and optionally potassium iodate, silicic acid and ascorbic acid. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the composition taught by Schardt to the composition used in the method taught by Klett-Loch to provide the instantly claimed invention because Schardt taught that compositions comprising zinc sulfate and sodium selenite were useful in the making of pharmaceuticals having the beneficial functional effect of treating alopecia in subjects in need thereof.

With regard to the claim limitation for administration of the claim-designated admixture for a period of time to elicit a desired effect, the adjustment of particular conventional working conditions (e.g., determining a result-effective means of administering the claimed ingredients for a period of time to induce a therapeutic effect), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of either one of ordinary skill in the art or the skilled artisan. Thus, as

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each of the references indicates that the various ingredients, process steps and experimental parameters used in the claimed method are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 77-83, 87-94 and 107-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klett-Loch (AA, US 6,013,279) and Schardt (NN, DE 10021310 A1) in view of Balch et al. (U), Navarra et al. (V) and Williams et al. (A*).

Applicant's claimed invention of Claims 77, 87 and 107 was set forth above. Applicant further claims the regime or regimens of Claims 77, 87 and 107 wherein said admixture also comprising iron in salt form; wherein said admixture also comprising magnesium in salt form; wherein said admixture also comprising copper in salt form; wherein said admixture also comprising magnesium in salt form; and, wherein said admixture also comprising manganese in salt form.

The method taught by the combined teachings of Klett-Loch and Schardt are set forth above. The method taught by the combined teachings of Klett-Loch and Schardt teaches the instantly claimed regime or regimen for increasing hair density and thus improving the quality and/or the appearance of a head of hair; and thus a regime or regimen for increasing hair density and thus treating alopecia except for wherein the

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admixture also comprises any of iron, magnesium, copper and/or manganese, each in salt form. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredients to the method taught by the combined teachings of Klett-Loch and Schardt to provide the instantly claimed invention because at the time the invention was made the instantly claimed ingredients were known in the art for their beneficial functional effects, as evidenced by the teachings of Balch, Navarra and Williams. Firstly, Balch beneficially teaches that a deficiency in zinc may result in hair loss, on page 29, under "*Zinc*". Moreover, on page 24, under "*Copper*", Balch teaches that copper is involved in hair coloring, works in balance with zinc and vitamin C, and aids in the production of blood; on page 25 under "*Iron*", Balch teaches that a lack of iron in the body may result in brittle hair and hair loss; on page 26 under "*Magnesium*", Balch teaches that magnesium is a vital catalyst in enzyme activity and maintains the body's pH balance; and, on page 26 under "*Manganese*", Balch teaches that manganese is essential for iron deficiency, is needed for utilization of vitamin B1 (thiamine) and vitamin E. Secondly, Navarra teaches that salts of iron (see pp. 105-108), salts of magnesium (see pp. 127-128), and salts of copper (see pp. 57-58) are pharmaceutically acceptable forms of the metallic elements for use in the making of cosmetic/pharmaceuticals for administration to humans; and, Williams teaches that salts of magnesium and manganese are useful in the making of vitamin/metal salt compositions comprising antioxidant vitamins, such as vitamins A, C and E, and vitamin B, for human consumption. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation

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of success to add the instantly claimed ingredients to the method taught by the combined teachings of Klett-Loch and Schardt to provide the instantly the instantly claimed regime or regimen because Balch taught that intake and absorption of zinc by humans are essential in maintaining the proper concentration of vitamin E in blood, and that zinc also increases the absorption of vitamin A; and, furthermore Balch taught that the intake of proper amounts of copper, iron, magnesium and manganese, as well as zinc, is important in the absorption of vitamins and maintaining the proper chemical balance of the body, maintaining overall health of the human body, as well as the health of the hair of individual (see page 12); and both Navarra and Williams suggested that salts of iron, magnesium, copper and manganese are desirable in the making of cosmetic/pharmaceuticals intended for the administration to humans for mineral supplementation because they are generally non-toxic and well absorbed by the human body and tolerated by humans when administered in therapeutic dose amounts; and, furthermore, like Balch, Navarra taught that vitamin A, vitamin C, vitamin B, iron, copper, zinc are particular determinants of hair loss, hair growth, hair baldness, hair growth patter, and the appearance of hair (see page 96).

With regard to the claim limitation for administration of the claim-designated admixture for a period of time to elicit a desired effect, the adjustment of particular conventional working conditions (e.g., determining a result-effective means of administering the claimed ingredients for a period of time to induce a therapeutic effect), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of either one of ordinary skill in the art or the skilled artisan. Thus, as

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each of the references indicates that the various ingredients, process steps and experimental parameters used in the claimed method are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 77, 78, 83, 84, 87, 88, 93, 107, 1-8, 113 and 114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klett-Loch (AA, US 6,013,279) and Schardt (NN, DE 10021310 A1) in view of Cooper et al. (B*) and Okada (OO, JP 04342516 A).

Applicant's claimed invention was set forth above.

The method taught by the combined teachings of Klett-Loch and Schardt are set forth above. The method taught by the combined teachings of Klett-Loch and Schardt teaches the instantly claimed regime or regimen except for wherein the zinc salt is either zinc oxide or zinc chloride; and wherein the selenium salt is selenocysteine. However, it would have been obvious to one of ordinary skill in the art to modify the composition used in the method for increasing hair density thus improving the quality and/or the appearance of a head of hair and the method for increasing hair density and thus treating alopecia taught by the combined teachings of Klett-Loch and Schardt by adding the claim-designated ingredients thereto and/or replacing the zinc salt and/or the selenium salt used therein to provide the instantly claimed invention because at the time

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the invention was made Cooper taught that pharmaceutically zinc compounds for use in the making of vitamin/metal salt cosmetic/pharmaceutical compositions include zinc sulfate, zinc sulfide and zinc chloride, in Column 8, lines 20-29; and, Okada taught a hair composition for suppressing yellowing of hair comprising a selenium salt, such as the claim-designated sodium selenite or selenocysteine. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to modify the composition used in the method for increasing hair density thus improving the quality and/or the appearance of a head of hair and the method for increasing hair density and thus treating alopecia taught by the combined teachings of Klett-Loch and Schardt by adding the claim-designated ingredients thereto and/or replacing the zinc salt and/or the selenium salt used therein to provide the instantly claimed invention because Cooper and Okada both suggested the claim-designated salts of zinc and the claim-designated salts of selenium are functional equivalents, each one for the other; and, furthermore, Cooper taught that the claim-designated zinc salts can be used in the making of vitamin/metal admixtures comprising the vitamins A, C, E and B and selenium; and, Okada taught that compositions comprising effective amounts of either sodium selenite or selenocysteine are useful in the making of therapeutic compositions to suppress the yellowing of hair.

With regard to the claim limitation for administration of the claim-designated admixture for a period of time to elicit a desired effect, the adjustment of particular conventional working conditions (*e.g.*, determining a result-effective means of administering the claimed ingredients for a period of time to induce a therapeutic effect),

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is deemed merely a matter of judicious selection and routine optimization which is well within the purview of either one of ordinary skill in the art or the skilled artisan. Thus, as each of the references indicates that the various ingredients, process steps and experimental parameters used in the claimed method are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Therefore, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 77-84, 87-94, 88, 93 and 107-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klett-Loch (AA, US 6,013,279) and Schardt (NN, DE 10021310 A1) in view of Cooper et al. (B*) and Okada (OO, JP 04342516 A), and further in view of Balch et al. (U), Navarra et al. (V) and Williams et al. (A*).

The combined teachings of Klett-Loch, Schardt, Cooper and Okada were set forth immediately above. The method taught by the combined teachings of Klett-Loch, Schardt, Cooper and Okada teaches the instantly claimed regime or regimen except for increasing hair density and thus improving the quality and/or the appearance of a head of hair; and thus a regime or regimen for increasing hair density and thus treating alopecia except for wherein the admixture also comprises any of iron, magnesium, copper and/or manganese, each in salt form. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredients to the method

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taught by the combined teachings of Klett-Loch, Schardt, Cooper and Okada to provide the instantly claimed invention because at the time the invention was made the instantly claimed ingredients were known in the art for their beneficial functional effects, as evidenced by the teachings of Balch, Navarra and Williams. Firstly, Balch beneficially teaches that a deficiency in zinc may result in hair loss, on page 29, under "*Zinc*".

Moreover, on page 24, under "*Copper*", Balch teaches that copper is involved in hair coloring, works in balance with zinc and vitamin C, and aids in the production of blood; on page 25 under "*Iron*", Balch teaches that a lack of iron in the body may result in brittle hair and hair loss; on page 26 under "*Magnesium*", Balch teaches that magnesium is a vital catalyst in enzyme activity and maintains the body's pH balance; and, on page 26 under "*Manganese*", Balch teaches that manganese is essential for iron deficiency, is needed for utilization of vitamin B1 (thiamine) and vitamin E.

Secondly, Navarra teaches that salts of iron (see pp. 105-108), salts of magnesium (see pp. 127-128), and salts of copper (see pp. 57-58) are pharmaceutically acceptable forms of the metallic elements for use in the making of cosmetic/pharmaceuticals for administration to humans; and, Williams teaches that salts of magnesium and manganese are useful in the making of vitamin/metal salt compositions comprising antioxidant vitamins, such as vitamins A, C and E, and vitamin B, for human consumption. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the instantly claimed ingredients to the method taught by the combined teachings of Klett-Loch, Schardt, Cooper and Okada to provide the instantly the instantly claimed

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regime or regimen because Balch taught that intake and absorption of zinc by humans are essential in maintaining the proper concentration of vitamin E in blood, and that zinc also increases the absorption of vitamin A; and, furthermore Balch taught that the intake of proper amounts of copper, iron, magnesium and manganese, as well as zinc, is important in the absorption of vitamins and maintaining the proper chemical balance of the body, maintaining overall health of the human body, as well as the health of the hair of individual, (see page 12); and both Navarra and Williams suggested that salts of iron, magnesium, copper and manganese are desirable in the making of cosmetic/pharmaceuticals intended for the administration to humans for mineral supplementation because they are generally non-toxic and well absorbed by the human body and tolerated by humans when administered in therapeutic dose amounts; and, furthermore, like Balch, Navarra taught that vitamin A, vitamin C, vitamin B, iron, copper, zinc are particular determinants of hair loss, hair growth, hair baldness, hair growth patter, and the appearance of hair (see page 96).

With regard to the claim limitation for administration of the claim-designated admixture for a period of time to elicit a desired effect, the adjustment of particular conventional working conditions (*e.g.*, determining a result-effective means of administering the claimed ingredients for a period of time to induce a therapeutic effect), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of either one of ordinary skill in the art or the skilled artisan. Thus, as each of the references indicates that the various ingredients, process steps and experimental parameters used in the claimed method are result variables, they would

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have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
March 3, 2007